IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

HERBERT FUSSMAN, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF RITA FUSSMAN Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendants.	)	Civil Action No.: 1:06CV00149-JAB-PTS **[Oral Argument Requested]**

NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT ON PROXIMATE CAUSATION

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Novartis Pharmaceuticals Corporation ("NPC") submits this memorandum in support of its Motion for Summary Judgment on Proximate Causation. Plaintiff cannot demonstrate that any alleged inadequate warning relating to NPC's drugs Aredia® and Zometa® caused any injury to Mrs. Fussman because he cannot show that her oncologist's prescribing decision would have been altered in any respect by a different warning. Accordingly, NPC is entitled to judgment in its favor.

STATEMENT OF NATURE OF MATTER

Plaintiff, as the administrator of the estate of Rita Fussman and on his own behalf, maintains this action seeking damages under North Carolina law for the alleged negligence of NPC in marketing its prescription drugs Aredia® and Zometa®. Plaintiff contends that Aredia® and Zometa® caused Mrs. Fussman to develop osteonecrosis of the jaw ("ONJ") and that NPC failed to adequately warn her prescribing physician, Dr. Heather Shaw ("Shaw"), of these alleged side effects. The only remaining claims in this case are based upon NPC's alleged failure to warn. *See* Memorandum Order, *In re Aredia and Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760 (M.D. Tenn. Aug. 13, 2009) (Ex. 1), at 4 (plaintiff's negligence claims are based on failure to warn), 6 (plaintiff's implied warranty claim is based on identical failure to warn allegation).

At the time NPC filed a motion for summary judgment in the MDL, it had not been able to schedule the deposition of Dr. Heather Shaw, Mrs. Fussman's prescribing physician, due to Dr. Shaw's medical disability. During motions practice before the MDL Court in Tennessee, plaintiff's counsel correctly characterized Dr. Shaw's

testimony as "the necessary evidence for [NPC's] learned intermediary defense."[1] Now, the deposition of Dr. Shaw has recently been taken. Following Dr. Shaw's deposition testimony, it is clear that plaintiff cannot link the allegedly inadequate warnings relating to Aredia® and Zometa® with the injuries that Mrs. Fussman allegedly sustained and, therefore, that he cannot satisfy the requirement of proximate causation imposed by North Carolina law. Accordingly, NPC seeks summary judgment.[2]

STATEMENT OF FACTS

Mrs. Fussman initially was diagnosed with breast cancer in 1986 and treated with a radical mastectomy and Tamoxifen (hormonal) therapy. Health Care Record of 5/4/01 (1561-0335) (Ex. 3); Transcript of Deposition of Rita Fussman at 69:12-70:5 ("Fussman Dep.") (Ex. 4). Mrs. Fussman's cancer was in remission until July 1999, when she was diagnosed with recurrent breast cancer and treated with surgery, radiation therapy, and further Tamoxifen. Health Care Record of 8/25/99 (1689-0032 to -0033) (Ex. 5); Fussman Dep. at 110-14 (Ex. 4).

[1] Plaintiffs' Opposition to Novartis Pharmaceuticals Corp.'s Motion for Summary Judgment in the *Fussman* Case at 1 ("Pl. Opp.") (Ex. 2). Plaintiff relied heavily on the assertion that "there is not a single case in North Carolina of summary judgment on failure to warn in a pharmaceutical claim being granted without deposing the prescribing physician." *Id.* at 12.

[2] For the purposes of this motion only, NPC does not contest other aspects of plaintiff's claims, *i.e.*, that its bisphosphonate drugs can be a substantial factor in the appearance of ONJ, that Mrs. Fussman had ONJ, and that NPC's warnings concerning ONJ were inadequate. If the case proceeds to trial, NPC will challenge all such contentions.

Mrs. Fussman began treatment with Aredia® on three-week intervals beginning in June 2001 on the recommendation of her oncologist, Dr. Heather Shaw. Health Care Record of 6/29/01 (1561-0237 to -0239) (Ex. 6). Dr. Shaw switched Mrs. Fussman from Aredia® to Zometa® in November 2001. Health Care Record of 11/29/01 (1561-0218 to -0221) (Ex. 7).

Dr. Shaw's medical records relating to Mrs. Fussman indicate that Dr. Shaw was aware of a potential association between bisphosphonates and ONJ at least as early as December 2003. Health Care Record of 12/10/03 (1561-0887 to -0889) (Ex. 8). She obtained this awareness originally from the medical literature in the form of a "case report." Transcript of Deposition of Dr. Heather Shaw (hereinafter "Shaw Dep.") at 72:20-73:12; 75:21-76:10; 78:2-6; 134:11-21 (aware of the possible association between bisphosphonates and osteonecrosis in December 2003); 205:16-19 (same) (Ex. 9).[3] The medical records of Mrs. Fussman's oral and maxillofacial surgeon ("OMS"), Dr. Thomas McGraw, indicate that Dr. Shaw revisited whether it was necessary for Mrs. Fussman to remain on bisphosphonate therapy in April 2004. Health Care Record of 4/19/04 (2362-0238) (Ex. 10). Notwithstanding her knowledge of the potential link between bisphosphonates and ONJ, Dr. Shaw, in consultation with Mrs. Fussman, Shaw Dep. at 79:1-17; 80:11-18, 96:15-97:14, kept Mrs. Fussman on monthly Zometa® until October

[3] Dr. Shaw also testified that she avoided pharmaceutical sales representatives and, rather, drew her own conclusions about drugs from the literature. *See*, *e.g.*, Shaw Dep. at 174:4-18. She could not recall ever having received information from an NPC sales representative that she believed was incorrect. Shaw Dep. at 203:21-204:8.

2004, when she elected to withhold Mrs. Fussman's Zometa® treatment for one month due to concern that her ONJ would worsen. Thereafter, again in consultation with Mrs. Fussman, Shaw Dep. *id.* at 110:12-17; 111:9-12, monthly infusions of Zometa® were resumed until June 2005, *id*. at 116:9-18, 216:18-22; *see* Health Care Record of 10/13/04 (1561-0785 to -0789) (Ex. 11); Health Care Record of 11/24/04 (1561-0760 to -0763) (Ex. 12); Health Care Record of 7/12/05 (1561-0559) (Ex. 13); Shaw Dep. at 216:18-22. Despite the fact that her cancer had metastasized to her bones,[4] Mrs. Fussman did not develop any skeletal related events (*e.g.* broken bones, spinal compression) while she was on Aredia® and Zometa®. Fussman Dep. at 131:6-32:4, 169:20-70:12, 173:4-10 (Ex. 4).

It cannot be disputed that Dr. Shaw continued to prescribe Zometa® to Mrs. Fussman long after Dr. Shaw was made aware that Zometa® had been associated with case reports of ONJ. Dr. Shaw actually reviewed the scientific literature allegedly connecting Zometa® to ONJ during one of Mrs. Fussman's visits and discussed it with her before jointly deciding to continue Zometa® treatment. Shaw Dep. 75:1-8; 75:16-25; 78:2-6; 79:12-17. "Given a patient with known bony metastases, [Dr. Shaw] would have said [to Mrs. Fussman], 'I recommend you stay on Zometa®.'" Shaw Dep. at 80:11-15; 96:20-25; 116:9-18. After the hiatus in October 2004, Dr. Shaw, with full knowledge of the risk of ONJ, decided that she needed to restart Zometa® because Mrs. Fussman "was beginning to have bony pain." Shaw Dep. at 118:14-21.

[4] Dr. Shaw testified that Mrs. Fussman's cancer had spread to her spine. *See* Shaw Dep. at 33:9-21.

As noted above, Mrs. Fussman began bisphosphonate treatments (Aredia®) in June 2001. Dr. Shaw unequivocally stated that, had she been aware of the alleged connection between bisphosphonates and ONJ as of June 2001, she still would have prescribed bisphosphonates to Mrs. Fussman. Shaw Dep. at 143:10-13.

It is absolutely clear therefore that, notwithstanding her actual knowledge that a possible connection had been drawn between Aredia® and Zometa® and ONJ, Dr. Shaw determined to continue to use of Zometa® as part of Mrs. Fussman's treatment regimen based on Mrs. Fussman's medical condition and Dr. Shaw's belief that the anticipated benefits of using Aredia® and Zometa® outweighed the risk of ONJ. Furthermore, the evidence establishes that, had Dr. Shaw known in June 2001 when she started Mrs. Fussman on Aredia® therapy of the alleged connection between bisphosphonates and ONJ, she would still have prescribed Aredia®. In these circumstances, the alleged inadequacy of the Aredia® and Zometa® labels cannot have been a proximate cause of any injury incurred by Mrs. Fussman.

QUESTION PRESENTED

Has plaintiff demonstrated the existence of a general issue of material fact that, had an adequate warning been given to Dr. Shaw, she would not have prescribed Aredia® and Zometa® to Mrs. Fussman and therefore that Mrs. Fussman would not have sustained her alleged injuries?

ARGUMENT

I. Standard for Summary Judgment

District courts are required to grant summary judgment when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Although the opposing party is entitled to have the facts construed in his favor, he cannot rest on his pleadings' allegations, *see* Rule 56(e), and "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Furthermore, courts must "view the evidence presented through the prism of the substantive evidentiary burden," so there must be sufficient evidence on which a jury could reasonably find for the plaintiff. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986). "Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules [of Civil Procedure]." *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986). "The mere existence of a scintilla of evidence in support of the plaintiffs' position will be insufficient" to defeat a defendant's summary judgment motion. *Anderson*, 477 U.S. at 252.

II. North Carolina Law Adopts the Learned Intermediary Rule, Under Which The Manufacturer of a Prescription Drug Need Only Warn the Prescribing Physician.

Under North Carolina law, NPC's duty to warn extends only to the *prescribing* physician, not to other medical personnel who later become involved with care of the patient. The North Carolina statute, N.C. Gen. Stat. § 99B-5(c), provides that:

> c) Notwithstanding subsection (a) of this section, no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product.

Although the statute became effective in 1996, some forms of the learned intermediary doctrine had been recognized earlier and applied, both by North Carolina courts and by federal courts interpreting North Carolina law. *See Holley v. Burroughs Welcome Co.*, 74 N.C.App. 736, 330 S.E.2d 228 (1985), *aff'd*, 318 N.C. 352, 348 S.E.2d 772 (1986) (warnings are to be given only to the party responsible for the patient's care); *Foyle v. Lederle Labs.*, 674 F. Supp. 530, 535-36 (E.D.N.C. 1987) (North Carolina would follow the overwhelming weight of law in other jurisdictions that warnings are to be given only to the party responsible for the patient's care).

The North Carolina statute applicable to this case requires plaintiff to prove at trial that NPC failed to give an adequate warning *to Dr. Shaw*, Mrs. Fussman's prescribing physician. Necessarily, if providing an adequate warning to Dr. Shaw would not have altered the outcome of her prescribing decisions for Mrs. Fussman, then proximate cause has not been established and plaintiff cannot recover. As shown below, plaintiff cannot create a genuine issue of fact on proximate case.

III. Plaintiff Has Not Shown a Genuine Issue of Material Fact that the Lack of an Adequate Warning of ONJ Proximately Caused Mrs. Fussman's Injuries.

In a products liability action under North Carolina law, the plaintiff must prove that the alleged product defect caused her injuries. *Ward v. Am. Med. Sys., Inc.*, 170 F.

Supp. 2d 594, 599 (W.D.N.C. 2001) (granting summary judgment to defendant) (citing *Jolley v. Gen. Motors Corp.*, 285 S.E.2d 301 (N.C. Ct. App. 1982)); *see Carlton v. Goodyear Tire & Rubber Co.*, 413 F. Supp. 2d 583, 588 (M.D.N.C. 2005) (citing *Red Hill Hosiery Mill, Inc. v. MagneTek, Inc.*, 530 S.E.2d 321, 326 (N.C. Ct. App. 2000)). Even negligence *per se* is not actionable unless the plaintiff can demonstrate that the complained-of negligence was the proximate cause of his injury. *Lynn v. Overlook Development*, 328 N.C. 689, 696, 403 S.E.2d 469, 473 (1991) (affirming trial court judgment for defendant). Proximate cause is defined as: "a cause producing the injurious result … in a continuous sequence, without which the injury would not have occurred …" *Goodman v. Wenco Foods, Inc.*, 333 N.C. 1, 18, 423 S.E.2d 444, 452 (1992).

Where an alleged failure to warn of the dangerous propensities of a drug is the crux of the action, numerous cases hold that the chain of proximate causation is broken unless plaintiff can prove that an adequate warning would have altered the prescribing physician's conduct.[5] *See, e.g., Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 645 (4th Cir. 1981) (affirming summary judgment against plaintiff who could not demonstrate that

[5] Under the learned intermediary doctrine, a manufacturer's duty to warn runs through the prescribing physician. NC Gen. Stat. § 99B-5(c) (no liability to manufacturer of a prescription drug if an adequate warning has been provided to the physician or other legally authorized person *who prescribes or dispenses* that prescription drug); *Baraukas v. Danek Med., Inc.*, No. 6:97CV00613, 2000 WL 223508 (M.D.N.C. Jan. 13, 2000) (Ex. 14); *Padgett v. Synthes, Ltd. (U.S.A)*, 677 F. Supp. 1329, 1335 (W.D.N.C. 1988) (citing *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) (South Carolina law)). *See generally* pp. 10-11 *infra*.

a manufacturer's failure to warn her prescribing physician concerning the risk of contracting Guillain-Barre Syndrome from an influenza vaccine was a cause in fact of her injury) (Virginia law); *Odom v. G.D. Searle & Co.*, 979 F. 2d 1001, 1003 (4th Cir. 1992) (upholding summary judgment for defendant IUD manufacturer because plaintiff did not demonstrate that an adequate warning would have altered the treating physician's prescription decision) (South Carolina law); *In re Zyprexa Prods. Liab. Litig.*, Nos. 04-MD-1596 (JBW), 07-CV-4505 (JBW), 2009 WL 2004540, at *13, *15 (E.D.N.Y. July 1, 2009) (prescribing doctor's awareness of the risk of weight gain and hyperglycemia from use of drug demonstrated that an alternative warning "would not have affected the treatment choices for plaintiff" and resulted in summary judgment for defendant) (Florida law) (Ex. 15); *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 555-56 (N.D. Tex. 2006) (manufacturer could not be held liable for inadequately warning of the risk of addiction from oxycontin absent evidence that an adequate warning would have altered the doctor's decision to prescribe) (Texas law); *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984 (C.D. Cal. 2001) (granting summary judgment where plaintiff could not demonstrate that a manufacturer's failure to warn of the risk of suicide associated with Zoloft would have altered the prescribing physician's conduct) (California law).[6]

[6]*See also v. Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 212-13 (5th Cir. 2008) (upholding summary judgment for pharmaceuticals corporation in failure to warn claim because plaintiff failed to show that the prescribing physician would have changed her prescribing decision in the presence of "adequate" warnings) (Texas law); *Grenier v. Med. Eng'g Corp.*, 99 F. Supp. 2d 759, 765-66 (W.D. La. 2000) (granting summary judgment for breast implant manufacturer because plaintiff did not show that the

Stanback is a particularly important precedent in the Fourth Circuit because the prescribing physician in that case had testified – just as Dr. Shaw did here – that he was aware of the risk of the adverse effect arising from use of the drug and prescribed it anyway. 657 F.2d at 645:

> Whatever may be said about Dr. Edmunds' policies and decisions from the standpoint of the patient, it is clear that they precluded Parke-Davis' failure to warn from having any effect whatsoever on Mrs. Stanback's injury. Even if Parke-Davis had fully warned Dr. Edmunds of any risk of GBS associated with flu vaccines at the time Mrs. Stanback received the second vaccination, the uncontradicted evidence establishes that Mrs. Stanback would have nevertheless received the flu vaccinations despite the slight risk, and would not have been informed of the risk. Dr. Edmunds' decisions and actions made in full knowledge of the information which an adequate warning would have contained therefore insulate Parke-Davis from any liability resulting from its failure to warn.

Here, the record reflects not only that Dr. Shaw likewise knew about the risk of ONJ, but that she discussed that risk with Mrs. Fussman before deciding to continue her Zometa® treatments and that she would have gone forward with Aredia® and Zometa® exactly as she did had she known of the ONJ risk in June 2001. Accordingly, Dr. Shaw's "decisions and actions made in full knowledge of the information which an adequate warning would have contained" break the causal chain and preclude liability. *See also Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977) (evidence showed that adequate warnings of risks associated with oral

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physician would have changed his prescribing decision in the presence of proper warnings).

contraceptives would not have made a difference in physician's treatment of plaintiff; plaintiff therefore failed to establish causation).

IV. Other Alleged Issues of Fact Are Either Not Material or Not Shown by More Than a Scintilla of Evidence.

Plaintiff contended previously and is likely to contend again that some other warning to Mrs. Fussman's dentists or oral surgeons might have averted certain dental procedures that Mrs. Fussman underwent and that the injury allegedly sustained by Mrs. Fussman is the result of such purportedly unnecessary procedures. *See*, *e.g.*, Pl. Opp. at 5 (Dr. Wagoner, Mrs. Fussman's dentist, would have avoided tooth extractions to the extent possible if he had known of a "relationship" between bisphosphonates and ONJ). In this regard, without any real analysis of North Carolina law, the MDL Court held that a genuine issue of material fact had been raised by plaintiff. However, as NPC has shown above, North Carolina law holds otherwise. Plaintiff has not cited any North Carolina case interpreting NC Gen. Stat. § 99B-5(c) in such a way as to require warnings to health care professionals who were not also prescribers of the prescription drug at issue. There is no basis for this Court to conclude that the North Carolina Supreme Court would so interpret the statute.

Thus, the theory articulated by plaintiff before the MDL Court that NPC had a legal duty to warn subsequent health care providers, *i.e.*, Mrs. Fussman's dentists and oral

surgeons, simply does not hold water in North Carolina.[7] Plaintiff would not be entitled to a jury instruction on that theory. Accordingly, that theory cannot be the basis of a ruling by this Court that plaintiff has raised a genuine issue of material fact.

Likewise, plaintiff is likely to contend that Mrs. Fussman testified at her deposition that, had she known of a risk of ONJ, she would not have consented to treatment with NPC's bisphosphonate drugs. *See* Pl. Opp. at 3-4.[8] Again, N.C. Gen. Stat. § 99B-5(c) eliminates this argument as a basis for a claim against the manufacturer. NPC did not have a duty to provide any warning directly to Mrs. Fussman, but only to her prescribing physician. Since a breach of that duty is the only basis for establishing liability in North Carolina, the showing above that such a breach was not a proximate cause of Mrs. Fussman's injuries requires entry of summary judgment.

In any event, in light of Dr. Shaw's testimony that she expressly discussed the risk of ONJ with Mrs. Fussman on repeated occasions and that Mrs. Fussman agreed to continue being treated with Zometa®, and in light of the corroborating medical records whose authenticity cannot be controverted, Mrs. Fussman's deposition testimony is insufficient to create a genuine issue of fact. A party cannot create a genuine factual

[7] Of course, under its diversity jurisdiction, the Court must apply North Carolina law. *See*, *e.g.*, *Universal Concrete Prods. v. Turner Constr. Co.*, 595 F.3d 527, 529 (4th Cir. 2010).

[8] The MDL Court accepted this as a further basis for denying NPC's original motion for summary judgment. However, because the MDL Court had already ruled that there was a genuine issue as to the conduct of Dr. Shaw (in the absence of her testimony), its holding regarding Mrs. Fussman's testimony is mere dictum.

issue through her testimony when the only conclusion that a reasonable trier of fact can reach is contrary to such testimony. Here, notwithstanding Mrs. Fussman's testimony, the only conclusion a reasonable trier of fact could reach is that Mrs. Fussman consented to continued treatment with Zometa® even though she was aware of the alleged association between her bisphosphonate therapy and ONJ. *See Quillin v. C.B. Fleet Holding Co.*, 328 F. App'x 195, at *6-*7 (4th Cir. 2009) (granting summary judgment in drug product liability case) (Maryland law).

In *Quillin*, the critical question was when plaintiff had been put on inquiry notice of his claim such that the statute of limitations began to run. Plaintiff's medical records showed that he had sufficient notice, at the time of his renal failure, that he had sustained an injury likely caused by the drug in question. Despite plaintiff's contrary position that it was only a recent newspaper article connecting the drug and renal failure that had put him on notice, the district court concluded that the date of accrual had been established by the medical records and therefore granted summary judgment. *Id*. The Fourth Circuit affirmed, noting that, in light of the medical records, a reasonable trier of fact could reach only one conclusion. *Id*. *See also Townley v. Norfolk & W. Ry.*, 887 F.2d 498, 501 (4th Cir. 1989) (incontrovertible documentary evidence established the date of accrual of plaintiff's claim for black lung disease notwithstanding his contrary testimony and the contrary testimony of other witnesses).

Just as in *Quillin*, the medical records here leave no room for any reasonable trier of fact to conclude anything other than that Mrs. Fussman consented to use of Zometa®

notwithstanding the risk of ONJ. Mrs. Fussman herself equivocated at her deposition, first admitting she did not know what she would have done had she been made aware. Fussman Dep. at 205:21-206:3. Only when questioned by her own counsel after a break in the deposition did Mrs. Fussman testify that she would not have received bisphosphonate treatment. *Id*. at 227:19-22. However, the medical records cited above establish conclusively that, indeed, she was made aware of the risk of the ONJ arising from her Zometa® treatment. *See id*. at 205:21-206:3.

CONCLUSION

NPC has demonstrated that there is no causal link between its alleged failure to warn that Aredia® and Zometa® could cause ONJ and Mrs. Fussman's injuries. Her prescribing doctor, Dr. Shaw, continued to prescribe Zometa® knowing about the alleged link. Dr. Shaw would have acted exactly as she did act in starting Mrs. Fussman on NPC's bisphosphonate drugs as of June 2001 had she known then of the alleged link between those drugs and ONJ. Because all remaining claims are based upon a failure to warn theory and because any such alleged failure was not a proximate cause of Dr. Shaw's prescriptions of Aredia® and Zometa®, the Court should grant NPC's motion for summary judgment.

May 10, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing **NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT ON PROXIMATE CAUSATION** using the CM/ECF system, which will send notification of such filing to CM/ECF participants: **Paul A. Daniels, Esq. and John J. Vecchione, Esq.** Bart T. Valad of Valad & Vecchione, PLLC was served via ECF service on his law partner John J. Vecchione, Esq.

This the 10th day of May 2010.

/s/ Katharine R. Latimer
Katharine R. Latimer